

Amendment to the Claims:

Please amend the claims as follows.

Please delete claims 5 and 11, without prejudice or disclaimer.

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A method for treating myeloma, comprising:

(A) (a) providing an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor,

wherein the anti-IL-6 receptor antibody has the same anticancer therapeutic mechanism of activity as an anticancer PM-1 antibody deposited as FERM BP-2998;

(b) providing a ~~nitrogen-mustard anticancer agent~~ melphalan; and

(c) administering the ~~nitrogen-mustard anticancer agent~~ melphalan in combination with the anti-IL-6 receptor antibody as part of a treatment regimen,

wherein the co-administration of ~~nitrogen-mustard anticancer agent~~ melphalan and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the ~~nitrogen-mustard anticancer agent~~ melphalan alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the ~~nitrogen-mustard anticancer agent~~ melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the ~~nitrogen-mustard anticancer agent~~ melphalan are formulated in one pharmaceutical composition.

Claim 2 (previously presented): The method according to claim 1, wherein the anti-IL-6 receptor antibody comprises a monoclonal antibody.

Claim 3 (previously presented): The method according to claim 2, wherein the monoclonal antibody comprises a PM-1 antibody deposited as FERM BP-2998.

Claim 4 (previously presented): The method according to claim 3, wherein the PM-1 antibody comprises a reshaped human PM-1 antibody.

Claim 5 (canceled)

Claim 6 (currently amended): The method according to claim 1, wherein (a) the ~~nitrogen mustard anticancer agent~~ is melphalan; or, (b) the method of (a), wherein the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 7 (currently amended): A method for treating myeloma, comprising

(A) administering an anti-IL-6 receptor antibody in combination with a ~~nitrogen mustard anticancer agent~~ melphalan as part of a treatment regimen,

wherein the anti-IL-6 receptor antibody has the same anticancer therapeutic mechanism of activity as an anticancer PM-1 antibody deposited as FERM BP-2998.

and the anti-IL-6 receptor antibody or the ~~nitrogen mustard anticancer agent~~ melphalan is administered in an amount to have a higher (synergistic) therapeutic effect for myeloma than when the ~~nitrogen mustard anticancer agent~~ melphalan is administered alone, or when the anti-IL-6 receptor antibody is administered alone; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the ~~nitrogen mustard anticancer agent~~ melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the ~~nitrogen mustard anticancer agent~~ melphalan are formulated in one pharmaceutical composition.

Claim 8 (previously presented): The method according to claim 7, wherein the anti-IL-6 receptor antibody comprises a monoclonal antibody.

Claim 9 (previously presented): The method according to claim 8, wherein the monoclonal antibody comprises a PM-1 antibody deposited as FERM BP-2998.

Claim 10 (previously presented): The method according to claim 9, wherein the PM-1 antibody comprises a reshaped human PM-1 antibody.

Claim 11 (canceled)

Claim 12 (currently amended): The method according to claim 7, wherein ~~the nitrogen mustard anticancer agent comprises~~ melphalan is formulated for oral administration, or for oral administration at 1 to 20 mg per day, every day or 1 to 6 times per week, or for high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 13 (currently amended): The method of claim 7 [[12]], wherein the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 14 (currently amended): The method of claim 7 [[12]], wherein the pharmaceutical composition ~~comprising a nitrogen mustard anticancer agent~~ is or the pharmaceutical compositions are administered simultaneously with the anti-IL-6 receptor antibody, and the ratio, is, when combined with daily oral administration of melphalan, 0.01 to 1000 fold (weight ratio) relative to the dose of melphalan.

Claim 15 (currently amended): The method of claim 1, wherein the pharmaceutical composition ~~comprising a nitrogen mustard anticancer agent~~ is or the pharmaceutical compositions are administered orally, by intravenous injection, drip infusion, intraarterial injection, intramuscular injection, intratumor injection, intrathoracic injection, or intraperitoneal injection, either systemically or locally.

Claim 16 (currently amended): The method of claim 1, wherein the pharmaceutical composition or the pharmaceutical compositions comprising anti-IL-6 receptor antibody is administered parenterally, by intravenous injection, drip infusion, intramuscular injection, intraperitoneal injection, subcutaneous injection, either systemically or locally; or, is administered as local dosage-forms, external preparations, local injections; or, as external preparations, liniments, ointments, gel, cream, emulsions, and liquids, tapes, plaster tapes, patches, nebulas, sprays or powders.

Claim 17 (currently amended): A method for treating a myeloma comprising:

(A) (a) providing at least one pharmaceutical composition comprising separately or in combination:

(i) an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor,

wherein the anti-IL-6 receptor antibody has the same anticancer therapeutic mechanism of activity as an anticancer PM-1 antibody deposited as FERM BP-2998, and

(ii) a ~~nitrogen mustard anticancer agent comprising~~ melphalan; and

(b) administering to an individual in need thereof the pharmaceutical composition as part of a treatment regimen,

wherein the co-administration of melphalan ~~nitrogen mustard anticancer agent~~ and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the melphalan ~~nitrogen mustard anticancer agent~~ alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan ~~nitrogen mustard anticancer agent~~ are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan ~~nitrogen mustard anticancer agent~~ are formulated in one pharmaceutical composition.

Claim 18 (previously presented): The method of claim 1, wherein treating myeloma comprises a life elongation effect.

Claim 19 (previously presented): The method of claim 7, wherein treating myeloma comprises a life elongation effect.

Claim 20 (previously presented): The method of claim 17, wherein treating myeloma comprises a life elongation effect.

Claim 21 (currently amended): A method for treating a myeloma comprising:

(A) (a) providing at least one pharmaceutical composition comprising separately or in combination:

(i) a recombinant monoclonal anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor, and

(ii) a ~~nitrogen-mustard anticancer agent comprising~~ melphalan; and

(b) administering to an individual in need thereof the pharmaceutical composition as part of a treatment regimen, wherein the administration comprises at least in part intravenous administration of melphalan or the anti-IL-6 antibody,

wherein the co-administration of melphalan ~~nitrogen-mustard anticancer agent~~ and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the melphalan ~~nitrogen-mustard anticancer agent~~ alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan ~~nitrogen-mustard anticancer agent~~ are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan ~~nitrogen-mustard anticancer agent~~ are formulated in one pharmaceutical composition, and at least one of the formulations is an intravenous formulation.